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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
VIVLEMORE, TRACY ANN	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 12/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/075,028	MITCHELL ET AL.	
	Examiner	Art Unit	
	Tracy Vivlemore	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 16-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

The restriction requirement issued in this application on June 2, 2004 is withdrawn in view of applicant's arguments in the communication of October 18, 2004.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

1. Claim 5 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 13 and 18 of prior U.S. Patent No. 6,013,487. This is a double patenting rejection.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-4, 6-12 and 16-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-15 and 18 of U.S. Patent No. 6,013,487. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application encompass the claims of the issued patent. Claim 13 of the '487 patent is drawn to a method of producing a chimeric RNA in a cell using a nucleic acid recognized by the

cell's nuclear splicing machinery comprising a target binding domain that targets a pre-mRNA expressed in the cell, a 3' splice region comprising a branch point, a pyrimidine tract and a 3' splice acceptor site, a spacer region that separates the 3' splice region from the target binding domain and a nucleotide to be trans-spliced to a target pre-mRNA. Claim 18 is drawn to a similar method that has a 5' splice site in place of the 3' splice region. Claims 1 and 2 of the instant application are drawn to a method of producing a chimeric RNA in a cell using a nucleic acid recognized by the cell's nuclear splicing machinery comprising a target binding domain that targets a pre-mRNA expressed in the cell, a 3' splice region comprising a 3' splice acceptor site and a nucleotide to be trans-spliced to a target pre-mRNA. Claim 1 also comprises a branch point and a pyrimidine tract. Claim 3 is drawn to a similar method that has a 5' splice site in place of a 3' splice region. Claim 16 is drawn to method similar to that of claims 1-3 wherein the nucleic acid molecule contains a 5' donor site and a 3' splice acceptor site. Claim 17 depends from claim 16 and recites the presence of a spacer region. Since claims 1-3 and 16 each use the open claim language "comprises", these claims encompass the additional component of the spacer region that is recited in claims 13 and 18 of the '487 patent. Instant claims 4 and 10-12 recite limitations identical to those of claims 14 and 15 of the '487 patent. Instant claims 6-9 and 18 recite limitations of the presence of a safety sequence or that the binding of the nucleic acid to the target is mediated by complementary, triple helix or protein-nucleic acid interaction. These limitations encompass the claims of the '487 patent as binding of the nucleic acid molecule to the target binding domain occurs through complementary interactions.

3. Claims 1-12 and 16-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-14 of U.S. Patent No. 6,083,702. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application encompass the claims of the issued patent. Claim 11 of the '702 patent is drawn to a method of producing a chimeric RNA in a cell using a nucleic acid recognized by the cell's nuclear splicing machinery comprising a target binding domain that targets a pre-mRNA expressed in the cell, a 3' splice region comprising a branch point, a pyrimidine tract and a 3' splice acceptor site, a spacer region that separates the 3' splice region from the target binding domain and a nucleotide to be trans-spliced to a target pre-mRNA. Claim 12 is drawn to a similar method that has a 5' splice site in place of the 3' splice region. The claims of the instant application are described in the previous double patenting rejection. Since instant claims 1-3 and 16 each use the open claim language "comprises", these claims encompass the additional component of the spacer region that is recited in claims 11 and 12 of the '702 patent. Instant claims 4 and 10-12 recite limitations identical to those of claims 13 and 14 of the '702 patent. Instant claim 5 recites the limitation of a spacer sequence between the 3' splice acceptor and the target binding domain, which appears in all the claims of the '702 patent. Instant claims 6-9 and 18 recite limitations of the presence of a safety sequence or that the binding of the nucleic acid to the target is mediated by complementary, triple helix or protein-nucleic acid interaction. These limitations encompass the claims of the '702 patent as binding

of the nucleic acid molecule to the target binding domain occurs through complementary interactions.

4. Claims 1-12 and 16-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-17 of U.S. Patent No. 6,280,978. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application encompass the claims of the issued patent. Claim 13 of the '978 patent is drawn to a method of producing a chimeric RNA in a cell using a nucleic acid recognized by the cell's nuclear splicing machinery comprising a target binding domain that targets a cystic fibrosis trans-membrane conductance regulator pre-mRNA expressed in the cell, a 3' splice region comprising a branch point, a pyrimidine tract and a 3' splice acceptor site, a spacer region that separates the 3' splice region from the target binding domain and a nucleotide to be trans-spliced to a target pre-mRNA. Claim 14 is drawn to a similar method that recites only a 3' splice acceptor site. The claims of the instant application are described in the previous double patenting rejections. Since instant claims 1-3 and 16 each use the open claim language "comprises", these claims encompass the additional component of the spacer region that is recited in claims 11 and 12 of the '978 patent. Instant claims 4 and 10-12 recite limitations identical to those of claims 16 and 17 of the '978 patent. Instant claim 5 recites the limitation of a spacer sequence between the 3' splice acceptor and the target binding domain, which appears in all the claims of the '978 patent. Instant claims 6-9 and 18 recite limitations of the

presence of a safety sequence or that the binding of the nucleic acid to the target is mediated by complementary, triple helix or protein-nucleic acid interaction. These limitations encompass the claims of the '978 patent as binding of the nucleic acid molecule to the target binding domain occurs through complementary interactions.

5. Claims 1-18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 19 of copending Application No. 09/756,096. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application would be encompassed by the claim of the '096 application. The claims of the instant application are described in the previous double patenting rejections. Claim 19 of the '096 application is drawn to a method of producing a chimeric mRNA molecule by contacting a pre-trans-splicing molecule with a target pre-mRNA under conditions in which a double trans-splicing reaction results in a portion of the pre-trans-splicing molecule being trans-spliced to a portion of the target pre-mRNA. Since claim 19 of the '096 application does not recite any limitations as to what is present in the claimed pre-trans-splicing molecule, the broad scope of this claim fully encompasses the scope and all limitations of the instant claims.

6. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claims 1-12 and 16-18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 50-56 of copending Application No. 09/838,858. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application fully encompass the claims of the co-pending application. Claim 50 of the '858 application is drawn to a method of producing a chimeric RNA in a cell using a nucleic acid recognized by the nuclear splicing components comprising a target binding domain that targets a non-human factor VIII pre-mRNA expressed in the cell, a 3' splice region comprising a branch point and a 3' splice acceptor site, a spacer region that separates the 3' splice region from the target binding domain and a nucleotide to be trans-spliced to a target pre-mRNA. Claim 51 is drawn to a similar method that recites only a 3' splice acceptor site. Claim 52 is drawn to a similar method that has a 5' splice site in place of the 3' splice region. Claim 53 recites the presence of a pyrimidine tract in the method of claim 50. The claims of the instant application are described in the previous double patenting rejections. Since instant claims 1-3 and 16 each use the open claim language "comprises", these claims encompass the additional component of the spacer region that is recited in claims 50-52 of the '858 application. Instant claims 4 and 10-12 recite limitations identical to those of claims 54 and 56 of the '978 patent. Instant claims 6-9 and 18 recite limitations of the presence of a safety sequence or that the binding of the nucleic acid to the target is mediated by complementary, triple helix or protein-nucleic acid interaction. Claim 55 of the '858 application recites the presence of

a safety sequence and binding of the nucleic acid molecule to the target binding domain occurs through complementary interactions.

8. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 1-5, 7-12 and 16-17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-17 and 39 of copending Application No. 09/941,492. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application fully encompass the claims of the co-pending application. Claim 13 of the '492 application is drawn to a method of producing a chimeric RNA in a cell using a nucleic acid recognized by the nuclear splicing components comprising a target binding domain that targets a human papilloma virus pre-mRNA expressed in the cell, a 3' splice region comprising a branch point and a 3' splice acceptor site, a spacer region that separates the 3' splice region from the target binding domain and a nucleotide to be trans-spliced to a target pre-mRNA. Claim 14 is drawn to a similar method that recites only a 3' splice acceptor site while claim 39 is drawn to a similar method reciting only the 3' splice acceptor site and no spacer region. Claim 15 is drawn to a similar method that has a 5' splice site in place of the 3' splice region. The claims of the instant application are described in the previous double patenting rejections. Since instant claims 1-3 and 16 each use the open claim language "comprises", these claims encompass the additional component of the spacer region that is recited in claims 13-15

of the '492 application. Instant claims 4 and 10-12 recite limitations identical to those of claims 16 and 17 of the '492 application. Instant claims 7-9 recite limitations that the binding of the nucleic acid to the target is mediated by complementary, triple helix or protein-nucleic acid interaction. These limitations encompass the claims of the '492 application as binding of the nucleic acid molecule to the target binding domain occurs through complementary interactions.

10. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (f) he did not himself invent the subject matter sought to be patented.
>
> (g)(1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by

> another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

Claims 1, 2 and 5-12 are rejected under 35 U.S.C. 102(a) as being anticipated by Puttaraju et al. (Molecular Therapy 2001, vol. 4, pages 105-114).

11. Claims 1 and 2 are drawn to methods of producing a chimeric RNA in a cell using a nucleic acid recognized by the cell's nuclear splicing machinery comprising a target binding domain that targets a pre-mRNA expressed in the cell, a 3' splice region comprising a 3' splice acceptor site and a nucleotide to be trans-spliced to a target pre-mRNA. Claim 1 also comprises a branch point and a pyrimidine tract. Claim 5 limits any of claims 1-4 by stating the nucleic acid also comprises a spacer region that separates the 3' splice region and the target binding domain. Claim 6 limits any of claims 1-4 by stating the nucleic acid also comprises a safety sequence that comprises one or more complementary sequences that bind to one or both sides of the 3' splice site. Claims 7-9 limit any of claims 1-4, 5 and 6, respectively, by stating the nucleic acid binds to the target pre-mRNA by complementary, triple helix or protein-nucleic acid interaction. Claims 10-12 limit any of claims 1-4, 5 and 6, respectively, by stating the nucleotide to be trans-spliced encodes a translatable polypeptide.

12. Puttaraju et al. disclose constructs of pre-trans-splicing molecules (PTMs) that contain a target binding region that interacts with the target through complementary binding, a 3' splice region that contains a 3' splice acceptor site, a branch point and a polypyrimidine tract (see figure 1). This construct is used in cell culture to produce chimeric RNAs that encode functional (ie, translatable) proteins (see page 107-108).

Puttaraju et al. also disclose at page 111, second column, that a "safety" region can be included in the construct to prevent non-specific splicing.

13. Thus, Puttaraju et al. disclose and anticipate claims 1, 2 and 5-15.

Claims 1-12 and 16-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Mitchell (US 6,013,487 January 11, 2000).

14. Claims 1 and 2 are drawn to methods of producing a chimeric RNA in a cell using a nucleic acid recognized by the cell's nuclear splicing machinery comprising a target binding domain that targets a pre-mRNA expressed in the cell, a 3' splice region comprising a 3' splice acceptor site and a nucleotide to be trans-spliced to a target pre-mRNA. Claim 1 also comprises a branch point and a pyrimidine tract. Claim 3 is drawn to a similar method that has a 5' splice site in place of a 3' splice region. Claim 16 is drawn to method similar to that of claims 1-3 wherein the nucleic acid molecule contains a 5' donor site and a 3' splice acceptor site. Claim 17 depends from claim 16 and recites the presence of a spacer region. Claim 4 limits claim 1 by stating the nucleic acid also comprises a 5' donor site. Claim 5 limits any of claims 1-4 by stating the nucleic acid also comprises a spacer region that separates the 3' splice region and the target binding domain. Claim 6 limits any of claims 1-4 and claim 18 limits claim 16 by stating the nucleic acid also comprises a safety sequence that comprises one or more complementary sequences that bind to one or both sides of the 3' splice site. Claims 7-9 limit any of claims 1-4, 5 and 6, respectively, by stating the nucleic acid binds to the target pre-mRNA by complementary, triple helix or protein-nucleic acid interaction.

Claims 10-12 limit any of claims 1-4, 5 and 6, respectively, by stating the nucleotide to be trans-spliced encodes a translatable polypeptide.

15. Mitchell discloses methods of producing chimeric RNA in a cell as described in the double patenting rejection in paragraph 2. At column 4, lines 33-53, Mitchell discloses the use of a safety sequence and at column 3, lines 7-31 disclose that binding can occur through complementary, triple helix or protein-nucleic acid interaction.

16. Thus, Mitchell discloses and anticipates claims 1-12 and 16-18.

Claims 1-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Mitchell et al. (WO 00/09734, February 24, 2000).

17. Claims 1-12 and 16-18 are described in the previous 102 rejections. Claims 13-15 depend from claims 1-4, 5 or 6, respectively and recite the limitation that the nucleotide to be trans-spliced to the target pre-mRNA contains a nonsense mutation.

18. Mitchell et al. disclose methods of producing chimeric RNA in cells using a pre-trans-splicing molecule comprising a target binding domain that specifically binds a pre-mRNA, a 3' splice region that includes a branch point, a pyrimidine tract and a 3'splice acceptor and/or a 5' splice donor site along with a spacer region that separates the splice region from the target binding region. On page 11, lines 16-18 Mitchell et al. disclose that the nucleotide can be engineered to have a translation stop codon, which would encompass use of a nonsense mutation. On the same page at lines 12-14 it is disclosed that the nucleotide can encode a functional protein. On page 13, line 20-page

14 line 5, Mitchell et al. disclose the use of a safety sequence which binds the nucleic acid through complementary base pairing.

19. Thus, Mitchell et al. disclose and anticipate claims 1-18.

Claims 1-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Mitchell et al. (US 6,083,702 July 4, 2000).

20. Claims 1-18 are described in the previous 102 rejections. Mitchell et al. disclose methods of producing chimeric RNA in a cell as described in the double patenting rejection in paragraph 3. At column 6, lines 50-55 Mitchell et al. disclose that the nucleotide can be engineered to have a translation stop codon, which would encompass use of a nonsense mutation. At column 8, lines 7-27, Mitchell et al. disclose the use of a safety sequence and at column 7, lines 3-10 and 38-46 disclose that binding can occur through complementary, triple helix or protein-nucleic acid interaction.

21. Thus, Mitchell et al. disclose and anticipate claims 1-18.

Claims 1, 2 and 5-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Puttaraju et al. (Nature Biotechnology 1999, vol. 17, pages 246-252).

22. Claims 1, 2 and 5-12 are described in the previous 102 rejections. Claims 13-15 depend from claims 1-4, 5 or 6, respectively and recite the limitation that the nucleotide to be trans-spliced to the target pre-mRNA contains a nonsense mutation. Puttaraju et al. disclose constructs of pre-trans-splicing molecules (PTMs) that contain a target binding region that interacts with the target through complementary binding, a 3' splice

region that contains a 3' splice acceptor site, a branch point and a polypyrimidine tract (see page 247 and figure 1). This construct is used in cell culture and in vivo to produce chimeric RNAs that encode functional (ie, translatable) proteins (see page 249-250 and figures 4 and 5). Puttaraju et al. also disclose at page 248 and in figure 2 that a "safety" region can be included in the construct to prevent non-specific splicing. On page 251 in the final paragraph, Puttaraju et al. contemplate the use of PTMs to deliver stop codon sequences, which would encompass a nonsense mutation.

23. Thus, Puttaraju et al. disclose and anticipate claims 1, 2 and 5-15.

Claims 1, 2 and 5-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Mansfield et al. (Gene Therapy 2000, vol. 7, pages 1885-1895).

24. Claims 1, 2 and 5-12 are described in the previous 102 rejections. Mansfield et al. disclose constructs of pre-trans-splicing molecules (PTMs) that contain a target binding region that interacts with the target through complementary binding, a 3' splice region that contains a 3' splice acceptor site, a branch point and a polypyrimidine tract (see page 1886 and figure 1). This construct is used in cell culture to produce chimeric RNAs that encode functional (ie, translatable) proteins (see page 1890 and figure 6). Mansfield et al. also disclose at pages 1888-1889 and in figure 5 that a "safety" region can be included in the construct to prevent non-specific splicing.

25. Thus, Mansfield et al. disclose and anticipate claims 1, 2 and 5-15.

Claims 1-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Mitchell et al. (US 6,280,978 July 4, 2000).

26. Claims 1-18 are described in the previous 102 rejections. Mitchell discloses methods of producing chimeric RNA in a cell as described in the double patenting rejection in paragraph 4. At column 12, lines 45-48 Mitchell et al. disclose that the nucleotide can be engineered to have a translation stop codon, which would encompass use of a nonsense mutation. At column 8, line 63 through column 9, line 17, Mitchell discloses the use of a safety sequence and at column 7, lines 46-65 and at column 8, lines 26-34 disclose that binding can occur through complementary, triple helix or protein-nucleic acid interaction.

27. Thus, Mitchell discloses and anticipates claims 1-18.

Claims 1-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Mitchell et al. (US 20030077754 A1 April 24, 2003).

28. Claims 1-18 are described in the previous 102 rejections. Mitchell discloses methods of producing chimeric RNA in a cell as described in the double patenting rejection in paragraph 5. In paragraph 68, Mitchell et al. disclose that the nucleotide can be engineered to have a translation stop codon, which would encompass use of a nonsense mutation. In paragraphs 75 and 76, Mitchell discloses the use of a safety sequence and in paragraph 71 disclose that binding can occur through complementary, triple helix or protein-nucleic acid interaction.

29. Thus, Mitchell discloses and anticipates claims 1-18.

Claims 1-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Mitchell et al. (US 20030148937 A1 August 7, 2003).

30. Claims 1-18 are described in the previous 102 rejections. Mitchell et al. disclose methods of producing chimeric RNA in a cell as described in the double patenting rejection in paragraph 7. At column 12, lines 45-48 Mitchell et al. disclose that the nucleotide can be engineered to have a translation stop codon, which would encompass use of a nonsense mutation. In paragraph 75, Mitchell et al. disclose that the nucleotide can be engineered to have a translation stop codon, which would encompass use of a nonsense mutation. In paragraphs 83 and 84, Mitchell discloses the use of a safety sequence and in paragraph 78 disclose that binding can occur through complementary, triple helix or protein-nucleic acid interaction.

31. Thus, Mitchell discloses and anticipates claims 1-18.

Claims 1-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Mitchell et al. (US 20030027250 A1 February 6, 2003).

32. Claims 1-18 are described in the previous 102 rejections. Mitchell et al. disclose methods of producing chimeric RNA in a cell as described in the double patenting rejection in paragraph 9. In paragraph 98 Mitchell et al. disclose that the nucleotide can be engineered to have a translation stop codon, which would encompass use of a nonsense mutation. In paragraphs 106 and 107, Mitchell et al. disclose the use of a

safety sequence and at column 7, lines 46-65 and in paragraph 101 disclose that binding can occur through complementary, triple helix or protein-nucleic acid interaction.

33. Thus, Mitchell et al. disclose and anticipate claims 1-18.

34. Claim 5 is directed to the same invention as that of claims 13 and 18 of commonly assigned US 6,013,487. The issue of priority under 35 U.S.C. 102(g) and possibly 35 U.S.C. 102(f) of this single invention must be resolved.

Since the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302), the assignee is required to state which entity is the prior inventor of the conflicting subject matter. A terminal disclaimer has no effect in this situation since the basis for refusing more than one patent is priority of invention under 35 U.S.C. 102(f) or (g) and not an extension of monopoly.

Failure to comply with this requirement will result in a holding of abandonment of this application.

35. Claims 1-12 and 16-18 are directed to an invention not patentably distinct from claims 11-14 of commonly assigned US 6,083,702. Specifically, the claims of the instant application encompass the claims of the issued patent.

36. Claims 1-12 and 16-18 are directed to an invention not patentably distinct from claims 13-17 of commonly assigned US 6,280,978. Specifically, the claims of the instant application encompass the claims of the issued patent.

37. Claims 1-18 are directed to an invention not patentably distinct from claim 19 of commonly assigned co-pending application 09/756,096. Specifically, the claims of the instant application are fully encompassed within the claims of the copending application.

38. Claims 1-12 and 16-18 are directed to an invention not patentably distinct from claims 50-56 of commonly assigned co-pending application 09/838,858. Specifically, the claims of the instant application encompass the claims of the issued patent.

39. Claims 1-5, 7-12 and 16-17 are directed to an invention not patentably distinct from claims 13-17 of commonly assigned co-pending application 09/941,492. Specifically, the claims of the instant application encompass the claims of the issued patent.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned US 6,083,702, US 6,280,978, application 09/756,096, application 09/838,858 and application 09/941,492 discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tracy Vivlemore whose telephone number is 571-272-2914. The examiner can normally be reached on Mon-Fri 8:45-5:15.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Tracy Vivlemore
Examiner
Art Unit 1635

TV
December 2, 2004

SEAN McGARRY
PRIMARY EXAMINER
1635